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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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MEDICAL DEVICE CLASSIFICATION PROCEDURES

Notice to Manufacturers

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Notice to Manufacturers

In his consumer affairs message to the Congress on October 30, 1969, the President directed the Secretary of Health, Education, and Welfare to determine the scope and nature of additional legislative controls necessary to protect the public against unreasonable risk of injury or illness from medical devices. In accordance with this directive, the Secretary established the Study Group on Medical Devices under the chairmanship of Theodore Cooper, M.D., then Director of the National Heart and Lung Institute. The Study Group (Cooper Committee) report, entitled "Medical Devices: A Legislative Plan," was released in September 1970.

The report is available for public review at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, during regular working hours Monday through Friday, The report may be purchased from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22151.

The Cooper Committee report called for the enactment of new device legislation which would include provisions requiring the systematic review of existing medical devices for the purpose of grouping them into three categories: Those devices subject to general regulatory controls but exempt from standard setting and premarket approval; those for which standards should be set and enforced; and those requiring premarket approval.

In December 1971, following the recommendations of the Cooper Committee, the Secretary forwarded proposed medical device legislation to Congress. The legislation was introduced but no action was taken on it during that session of Congress. Legislation was again introduced in both the House of Representatives and the Senate in 1973. Hearings on the new medical device legislation were held by the Subcommittee on Health, Committee on Labor and Public Welfare of the Senate in September 1973, and by the Subcommittee on Public Health and Environment, Committee on Interstate and Foreign Commerce of the House of Representatives in October 1973. A medical device bill was passed in the Senate on February 1, 1974, but the House of Representatives did not enact device legislation during the 93rd Congress. During the 94th Congress, a medical device bill was introduced on March 26, 1975 in the House of Representatives. Soon after, on April 17, 1975, the Senate passed a medical device bill containing provisions comparable to those passed during the previous Congress and forwarded it to the House of Representatives for consideration.

Pending introduction and enactment of appropriate medical device legislation, the Secretary requested the Commissioner of Food and Drugs to develop an inventory of existing medical devices. The inventory was developed in 1971, primarily from information obtained from questionnaires sent to over 4,000 manufacturers in the United States. Approximately 2,000 replies were received. About 1,000 firms in the United States were identified as manufacturers of medical devices. A list of approximately 8,000 devices was compiled. That list subsequently has been broken down into the 14 classification panel specialty areas and is available through Bureau of Medical Devices and Diagnostic Products (BMDDP), HFK–100 (Division of Compliance), 5600 Fishers Lane, Rockville MD 20852.

The Secretary also requested the Commissioner to classify such devices into the three categories called for in the Cooper Committee report. The device classification process was preceded by the work of ad hoc committees composed of experts from the orthopaedic and cardiovascular specialty areas which were organized to develop and recommend general procedures and criteria that could be used to formulate a system for the classification of all medical devices. The recommendations of these committees were reviewed and revised by the Food and Drug Administration with the assistance of the health professions and regulated industry. These efforts resulted in the development of a classification logic system for determining one or more appropriate levels of control for any medical device. The resulting device classification system included a series of questions relating to a device's characteristics that are determinative of its appropriate classification. These questions have been incorporated into a classification logic system which is the central element in the classification process.

The classification process itself was initiated by dividing all devices into 14 separate categories generally based on medical specialties: Orthopaedic; cardiovascular; dental; anesthesiology; obstetrical and gynecological; gastroenterology and urology; radiology; neurology; ear, nose and throat; ophthalmic; general and plastic surgery; physical medicine (physiatry); diagnostic products; and general hospital and personal use. The initial device categorization list is on public display in the office of the Hearing Clerk, Food and Drug Administration, at the address given above.

Fourteen classification panels were established corresponding with the medical specialties above and comprised of experts skilled in the use of, or experienced in the development, manufacture, or utilization of medical devices. Panel members have been selected and the panels are presently functioning in review and classification of devices that fall within their respective areas.

The 14 classification panels and their members are listed below. Of these 14 panels, the first four were established from lists of experts compiled by the Commissioner. (See 38 FR 19060, July 17, 1973.) Prior to selecting members for 9 of the other 10 panels, an opportunity was provided, through notices published in the FEDERAL REGISTER, for interested persons to nominate qualified individuals with diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions (38 FR 34353, Dec. 13, 1973; 39 FR 7191, Feb. 25, 1974; 39 FR 12268, Apr. 4, 1974). It was from these nominations that the Commissioner appointed the expert panel members to the panels. The tenth panel, the diagnostic products panel, received nominations from professional clinical laboratory and scientific associations and the panel members were chosen on the basis of expertise in the area of in vitro diagnostic products. Opportunity was provided for the nomination of a nonvoting consumer and industry representative to each of the 14 panels and from these the Commissioner appointed consumer and industry panel members to all 14 panels. Full-time employees of the Food and Drug Administration were not appointed as panel members.

The membership of the panels is listed below:

Orthopaedic:
- Victor H. Frankel, M.D., Ph.D., Chairman.
- Charles H. Epps, Jr., M.D.
- Floyd H. Jergensen, M.D.
- Jacquelin Perry, M.D.
- Robert F. Hochman, Ph.D.
- Consumer liaison: Arthur L. Foley, M.D., Ph.D.
- Industry liaison: Vacant.

Cardiovascular:
- John J. Collins, Jr., M.D., Chairman.
- Nina Starr Braunwald, M.D.
- Clarence Dennis, M.D., Ph.D.
- Jerome Liebman, M.D.
- Arthur Miller, Sc.D.
- Gabriel Gregoratos, M.D.
- Leslie A. Geddes, Ph.D.
- Consumer liaison: Margaret L. Arnold.
- Industry liaison: Kenneth D. Serkes, M.D.

Dental:
- John W. Stanford, Ph. D., Chairman.
- Garrett V. Ridgley, D.D.S.
- W. Arthur George, D.D.S.
- George E. Myers, D.D.S.
- Floyd A. Peyton, D. Sc.
- Harold E. Boyer, D.D.S.
- Frank L. Baasch.
- Consumer liaison: Claire Davis.
- Industry liaison: Robert H. Mercer.

Anesthesiology:
- Leslie Rendell-Baker, M.D., Chairman.
- James A. Meyer, M.D., LTC, MC.
- Eugene L. Nagel, M.D.
- Stanley W. Weitzner, M.D.
- Penelope Cave Smith, M.B.
- Henning Pontoppidan, M.D.
- John P. Swope, M.D.
- Consumer liaison: Alma Ashley.
- Industry liaison: Chalmers M. Goodyear.

Gastroenterology and Urology:
- George R. Nagamatsu, M.D., Chairman.
- Irving M. Bush, M.D.
- Joseph B. Dowd, M.D.
- Joyce D. Gryboski, M.D.
- W. Ray Hancock, M.D.
- Victor F. Scott, M.D.
- Orvar Swenson, M.D.
- Consumer liaison: S. Nathan Zilber.
- Industry liaison: Lawrence E. Curtiss.

Obstetrical and Gynecological:
- Horace E. Thompson, M.D., Chairman.
- Juel P. Borders, M.D.
- Richard P. Dickey, M.D., Ph.D.
- Theodore H. Freilich, D.O.

Emanuel A. Friedman, M.D.
Charlotte H. Kerr, M.D.
Melvin R. Silkov, Ph.D.
Consumer liaison: Charlotte Browne-Mayers.
Industry liaison: Arnold E. Gorman.

Diagnostic Products:
Ronald H. Laessig, Ph.D. Chairman.
Marjorie L. Bissett, Ph.D.
Raymond E. Vanderlinde, Ph.D.
Roy N. Barnett, M.D.
Morton A. Madoff, M.D.
James E. Bowman, Jr., M.D.
Daniel T. Teitelbaum, M.D.
Elizabeth A. McGrew, M.D.
Doris L. Ross, Ph.D.
Grant T. Wernimont, Ph.D.
Noel R. Rose, M.D., Ph.D.
Bernadette B. Bourne, Ph.D.
Thomas F. Dutcher, M.D.
Consumer liaison: Thelma M. Bigelow.
Industry liaison: Richard G. Nadeau, Ph. D.

General Hospital and Personal Use:
George H. C. Stobie, M.D., Chairman.
Ruth H. Bryce, R.N.
Philip B. Johnson, M.D.
Rosita S. Pildes, M.D.
William R. Cole, M.D.
William E. Matory, M.D.
Edith Heideman, R.N.
Consumer liaison: Vacant.
Industry liaison: Theodore J. Medrek, M.D.

Neurology:
Charles Burton, M.D., Chairman.
John S. Barlow, M.D.
William B. Jarzembski, Ph.D.
Micheline Maccario, M.D.
Joseph T. McFadden, M.D.
Blaine S. Nashold, M.D.
Harold Stevens, Ph.D., M.D.
Consumer liaison: Valerie W. Bulkeley.
Industry liaison: Charles D. Ray, M.D.

Ear, Nose & Throat:
Harry W. McCurdy, M.D., Chairman.
Rita B. Eisenberg, Sc.D.
James Jerger, Ph.D.
Arthur F. Niemoeller, D.Sc.
F. Blair, Simmons, M.D.
Gabriel F. Tucker, Jr., M.D.
Walter C. McLean, M.D.
Consumer liaison: Jean L. McCarrey.
Industry liaison: Russell Lee Thompson.

General & Plastic Surgery:
Harold Laufman, M.D., Ph.D., Chairman.
Bohn D. Allen, M.D.
Louis R. M. Del Guercio, M.D.
John B. Lynch, M.D.
Frederick J. McCoy, M.D.
Rose Marie McWilliams, R.N.
Alma D. Morani, M.D.
Consumer liaison: Michael C. Watson, M.D.
Industry liaison: Paul C. Haffey.

Ophthalmic:
Robert D. Reinecke, M.D., Chairman.
Richard F. Brubaker, M.D.
Jess B. Eakridge, Ph.D.
Theodore Lawwill, M.D.
Donald G. Pitts, Ph.D.
Abraham Schloesman, M.D.
Michael A. Wainstock, M.D.
Consumer liaison: Gladys V. Haugen, Mrs.
Industry liaison: Charles J. Koester, Ph.D.

Physical Medicine (Psychiatry):
Margaret M. Kenrick, M.D., Chairman.
W. Hadely Hoyt, D.O.
James L. Cockrell, Ph.D.
Joy Cordery
Justus F. Lehmann, M.D.
Herbert W. Park III, M.D.
Herman Wing, M.D.
Consumer liaison: Hollis K. Russell, Jr.
Industry liaison: Leslie W. Partridge.

Radiology:
William J. Tuddenham, M.D., Chairman.
Leslie L. Alexander, M.D.
Valerie A. Brookeman, Ph.D.
Charles A. Kelsey, Ph.D.
Robert D. Moseley, Jr., M.D.
Andrew K. Poznanski, M.D.
Arch W. Templeton, M.D.
Consumer liaison: Richard A. Victor.
Industry liaison: William D. Ashby.

The curriculum vitae of panel members are on public display at the office of the Hearing Clerk, Food and Drug Administration, address noted above.

The provisions of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act presently authorize the Food and Drug Administration to engage in medical device classification. The Commissioner has concluded that, pending enactment of new legislation containing specific classification procedures, interim procedures consistent with the recommendations of the Cooper Committee and proposed legislation should be published in order to formalize, on a temporary basis, the current classification process. These procedures are set forth below. They are designed to enable the Commissioner to determine which devices should be subject to general controls, performance standards, or premarket approval. Further, they provide to manufacturers and importers of devices early notice and information that they can use to enable them to prepare for the application of such controls, standards, or approval to the devices handled by them, when new legislation is enacted.

The Commissioner has reviewed the classification logic system and has concluded that it is consistent with the proposed legislation and that it represents a reasonable mechanism for device classification. Accordingly, he finds that this system shall remain in effect until or unless modified by legislation.

Under the proposed legislation, in vitro diagnostic products are regulated as devices. The present system can also be applied to these products. Accordingly, the diagnostic products classification panel is applying this system.

The following interim procedures relating to the classification of medical devices intended for human use (including in vitro diagnostic products) are hereby adopted.

INTERIM CLASSIFICATION PROCEDURES

1. *Panel membership.* The procedure for the nomination of members to serve on medical device classification panels already has been the subject of previous notices that were published in various issues of the FEDERAL REGISTER. The citations to these notices are: July 17, 1973 (38 FR 19060); December 13, 1973 (38 FR 34353); February 25, 1974 (39 FR 7191); April 4, 1974 (39 FR 12268). The Commissioner concludes that this process is consistent with the proposed legislation and that no change is warranted at this time.

A panel in existence prior to this notice shall continue in existence in accordance with the terms of the charter by which the panel was established. Members appointed to such panels will continue to serve for the duration of the panel, or until their terms of appointment expire, they resign, or are removed from membership by the Commissioner.

Appointment of new panel members shall be initiated by a notice published in the FEDERAL REGISTER calling for nomination of members. Scientific, trade, consumer, and professional organizations, and interested individuals may submit nominations in accordance with the procedures published in the FEDERAL REGISTER notices cited above.

Experts appointed to a panel will be qualified by training, education, or experience to evaluate the safety and effectiveness of the devices to be referred to the panel to which they are appointed. Such persons will be skilled in the use of, or experienced in, the development, manufacture, or utilization of such devices. The panel membership will consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, or other related professions; and there will be a non-voting consumer and industry representative on each panel. The consumer and industry representatives will be selected to represent the interests of and serve as liaison with interested individuals, associations, and organizations.

Full-time employees of the Food and Drug Administration will not be appointed as panel members but do serve as executive secretaries to panels. These executive secretaries will have no vote.

2. *Device classification logic system.* Each device subject to classification shall be sequentially carried through the device classification logic system to determine which of the following controls apply: General controls, performance standards, or premarket approval. The determination is made after the consideration of 18 logic system questions relating to the safety and effectiveness characteristics of the device under consideration. All human medical devices will be subject to the minimum level of general controls; some such devices also will be subject to other controls. The 18 classification logic system questions are designed to designate those devices for which additional controls are or are not appropriate or necessary. The least restrictive level of control will be determined consistent with the overall objective of ensuring that the device is both safe and effective. The level of control selected for a particular device must be the most practical means of materially reducing whatever risk is associated with it, consistent with appropriate public health considerations. Although experts in the use and application of the device under review can best utilize the classification system, it is designed so that one generally familiar with a particular device can classify the device by using the system.

The following device classification logic system which has been in use by the panels is adopted:

Question 1: Is the device custom made?

Answer: Yes—Go to question 2. No—Go to question 3.

Question 2: Although the device is custom made, can standards be applied?

Answer: Yes—Appropriate and applicable standards apply; go to question 17. No—Go to question 17.

Question 3: Is the device life-sustaining or life-supporting?

Answer: Yes—Go to question 5. No—Go to question 4.

Question 4: Is the device or diagnostic information derived from use of the device potentially hazardous to life or good health when properly used?

Answer: Yes—Go to question 5. No—Go to question 7. Do not know—Go to question 5.

Question 5: Is the device of such a nature that: (a) sufficient scientific and medical data exist from which adequate standards governing the device safety and efficacy could now be established; and; (b) development and application of such a standard would be adequate to control the device?

Answer: Yes—Go to question 7. No—Go to question 6. Do not know—Go to question 6.

Question 6: Is the device currently in use and marketed in the United States?

Answer: Yes—Premarket approval and general controls apply; go to question 7. No.—(Assuming that the device is ready for and will be introduced into full scale marketing.) Premarket approval and general controls apply. Go to question 7.

Question 7: When the device is used, is it remote from the body? (Remote means no physical or energy connection to the body nor is it used as a part of or a delivery system for gases, fluids or other materials to or from the body.)

Answer: Yes—Go to question 14. No—Go to question 8. (Device is not remote if it is: (1) associated with the body through some form of energy transmission or conduction or used as a delivery system for gases, fluids or other materials to or from the body; (2) used on surface of the body; (3) used in contact with an internal body surface or cavity or used as a short-term implant; and/or (4) used as a long-term implant that is designed to be inserted into the body and reside indefinitely within the body.) Do not know—Go to question 8.

Question 8: Is the device powered by a nonmanual external or internal source (such as electrical, pneumatic, nuclear, etc.)?

Answer: Yes—Go to question 9. No—Go to question 13.

Question 9: Will the use of device or failure of power or device power source present a potential hazard to the patient?

Answer: Yes—Electrical, mechanical or some other safety standard which reflects the powered nature of the device will apply. Go to question 10. No—Go to question 10. Do not know—Electrical, mechanical or some other safety standard which reflects the powered nature of the device will apply; go to question 10.

Question 10: Does the device emit and/or inject any form of energy to or into the body?

Answer: Yes—Go to question 11. No—Go to question 13.

Question 11. Have the energy levels used been shown to be acceptable?

Answer: Yes—Go to question 12. No—Energy level standards apply. Go to question 12.

Question 12: Will malfunction of the device result in safe energy levels?

Answer: Yes—Go to question 13. No—Energy level standards for the device apply. Go to question 13. Do not know—Energy level standards for the device apply; go to question 13.

Question 13: Does the device use material for contact with the body which is generally acceptable or has known and acceptable properties which can be provided with no additional control requirements?

Answer: Yes—Go to question 14. No—Standards for material applicable for that portion of the device which comes in contact with the body, body fluids, or materials delivered to the body; go to question 14. Do not know—Standards for material applicable for that portion of the device which comes in contact with the body fluids, or materials delivered to the body; go to question 14.

Question 14: Does the device have any known hazards, limitations, or shortcomings which can be avoided by promulgation of Federal regulations applicable to the device in question?

Answer: Yes—Go to question 15. Proscriptions apply (limitations, hazards, difficulties, problems of a device or class of devices which can be controlled by specific regulations concerning the devices in question). No—Go to question 15.

Question 15: If the device performs some measurement function, should the accuracy, reproducibility or limitations of the information supplied be clearly indicated to the user by appropriate labeling, instructions, or precautions?

Answer: Yes—Go to question 16. Measurement characteristics apply (performance, accuracy, or use considerations which should be clearly indicated in the labeling so this information is readily available to the user). No—Go to question 16.

Question 16: Does the device have performance characteristics which should be maintained at a satisfactory level, such level having general agreement among the user groups?

Answer: Yes—Specific performance standards apply. Go to question 17. No—Go to question 17.

Question 17: Is the device used with other devices in such a way that the system in which it is used can be hazardous if the system is not assembled, used or maintained in a satisfactory fashion?

Answer: Yes or do not know—System considerations and general controls apply. (Systems considerations, as a control category, at present are beyond the jurisdiction of the Federal Food, Drug, and Cosmetic Act but should be encouraged by working with outside organizations (Inter-Society Commission for the Accreditation of Hospitals, American Hospital Association, local and state regulatory authorities, medical societies, etc.) which may have more jurisdiction and authority.) No—General controls apply.

Question 18: Is the device potentially hazardous to the fetus or the gonads when properly used?

Answer: Yes or do not know—The device will be reviewed by the obstetrical and gynecological and the classifying panels jointly for further classification.

3. *Panel meetings—open and closed sessions.* One portion of any panel meeting shall be open to provide an opportunity for all interested persons to present oral data, technical information and views. The panel also may meet in closed session for deliberation and consideration of data and information exempt from public disclosure. Only panel members (including the industry and consumer representatives) and such other FDA employees and consultants as may be authorized by the Commissioner shall be permitted to attend a closed session.

4. *Submission of data to the committee—opportunity for presentation.* The Commissioner believes that all interested persons should have an opportunity to submit relevant data, technical information, and views to the Food and Drug Administration for consideration by the applicable device classification panel in its deliberations. Not less than 15 days prior to each meeting, a notice will be published in the FEDERAL REGISTER stating the name of the classification panel which is meeting; the date, time, and location of the meeting; the time of the open and closed portions of the meeting (including the reasons for closing); the time specifically set aside for oral statements by interested persons and other public participation; a statement that written submission may be made to the panel at any time; the name, address, and telephone number of the contact person for the panel; and the list of all devices whose classification will be considered at the meeting. The list of devices will also be available by mail prior to the publication of the notice of the meeting in the FEDERAL REGISTER, if requested in writing from the contact person for the panel.

Any individual or organization may present to the panel oral data, technical information and views relating to the proper classification of a device. Additionally, individuals or organizations may present data, technical information and views in writing.

Individuals and organizations requesting an opportunity for oral presentation shall inform the contact person, no later than 10 days prior to the panel meeting, of that intention, with a brief statement of the general nature of the proposed presentation is expected to begin. Wherthe names and addresses of proposed participants, and references to any data to be relied upon. The contact person shall determine the time to be allocated to each oral presentation and shall inform the individual or organization of the time allocated and the approximate time the presentation is expected to begin. Whenever possible, all written data and information to be discussed in the presentation to the panel shall be furnished in advance to the contact person who shall distribute it to the panel members.

Individuals or organizations submitting written presentations shall forward 15 copies to the contact person. These shall be accompanied by a brief summary of the data, technical information and views presented, as well as names and addresses of the presentors. Material not received far enough in advance of the meeting to allow distribution to the panel members prior to that meeting will be given to the panel members for their consideration at the next meeting.

Presentations may be given to a complete panel or a subpanel of a panel. All presentations shall be open to the public, except to the extent matters are presented that are prohibited from public disclosure, pursuant to the provisions of 21 CFR Part 4. The panel may establish a cut-off date after which submissions of data, technical information or views will not be considered, unless after a preliminary review the panel determines that in the public interest they should be reviewed and considered in depth.

After considering the written comments and oral presentations, the panel, through the use of the classification logic system set out in paragraph 2, shall decide on the appropriate classification for each specific device or class of de-

vices. The panel's decision shall be documented by a completed classification logic system questionnaire for the device.

5. *Release of data and information submitted to panel.* Two types of information generally may be presented to the medical device classification panels: (a) Manufacturing data including design, production, quality control, and similar information, and (b) data relating specifically to safety and effectiveness. The release of such data and information is governed by the new public information regulations in 21 CFR Part 4 as promulgated in the FEDERAL REGISTER of December 24, 1974 (39 FR 44602), as follows:

(a) *Manufacturing data.* All manufacturing data and information submitted to a medical device classification panel including data relating to design, production, quality control, and similar information which is used in one's business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it shall be retained as confidential trade secret information and not released to the public at any time, unless it has previously been disclosed in a lawful manner to any member of the public or is abandoned and thus is no longer confidential.

(b) *Safety and effectiveness data.* The release of safety and effectiveness data relating to medical devices shall be handled in the same manner as such data are handled for drugs, as discussed in detail in the preamble to the notice promulgating the new public information regulations published in the FEDERAL REGISTER of December 24, 1974 (39 FR 44602). Under the Federal Food, Drug, and Cosmetic Act, new drugs are regulated by private licenses rather than public regulations. No one may market a new drug without first obtaining his own approved new drug application. Accordingly, the Commissioner has concluded that the safety and effectiveness data for new drugs fall within the trade secrets exemption and thus are not available for public disclosure, unless the applicant previously has made the information public, or the drug has been disapproved or withdrawn from the market, or the drug has reached the stage where it may be marketed without submission of such data to the agency for approval.

In contrast to new drugs, antibiotic drugs are regulated by public regulation. Anyone who meets the requirements of the regulation may lawfully market the antibiotic drug without obtaining any further approval. Accordingly, the Commissioner has concluded that the safety and effectiveness data for antibiotic drugs do not fall within the trade secrets exemption and are available for public disclosure immediately.

Because premarket approval of a device under the proposed legislation follows the same individual product license approach as premarket approval of new drugs, the Commissioner concludes that the economic value of the safety and effectiveness data for medical devices subject to premarket approval is similar to such data included in new drug applications. Accordingly, the release of information for devices which are classified in this category will be handled in the same manner as for new drugs. Similarly, where a device is classified as subject only to standards, which are public regulations, the release of information will be handled in the same manner as for antibiotic drugs.

However, the Commissioner will not be able to determine the confidentiality of safety and effectiveness data submitted for devices until he makes a final decision on classification. Therefore, safety and effectiveness data and information submitted to a panel, except for material that has previously been disclosed to the public, shall be considered confidential until a decision on final classification is reached. Upon final classification by the Commissioner, data and information which fall within the confidentiality provisions established in 21 CFR Part 4, or which relate to the safety and effectiveness of devices determined to require premarket approval, shall be retained as confidential. Safety and effectiveness data and information for those devices classified in either the performance standard or general regulatory controls categories shall, within 30 days after such final classification, be made available to the public, unless the person who submitted the information demonstrates that it should remain confidential in accordance with the provisions of 21 CFR Part 4.

All views expressed by non-panel members with respect to the proper classification of a device shall be available to the public upon receipt of such submission. The industry and consumer representatives and other panel members may relate and discuss all aspects of the closed portions of a panel meeting (including summary data), except those involving trade secrets, confidential commercial or financial matters, or any other matter for which FDA or the panel concludes that disclosure would be premature. The views of individual panel members shall not be disclosed.

6. *Release of panel's tentative classification recommendations.* The tentative classification recommendations of a panel for each device or class of device, in the form of a completed classification logic system questionnaire, will be available after each panel meeting from the Hearing Clerk, Food and Drug Administration, address noted above. Interested persons will then have an opportunity to present information to the panel relative to the tentative classification of a device pursuant to the procedures set forth in paragraph 4.

The minutes of the panel meetings shall include the proposed classification of the devices considered at the meeting. The minutes, as approved by the panel and certified by the chairman, excluding matter nondisclosable pursuant to 21 CFR Part 4, will be available from the Hearing Clerk.

Periodically, a FEDERAL REGISTER notice of availability will be issued listing the tentative classification conclusions of the classification panels and the availability of the tentative classification results and questionnaires.

These interim procedures shall remain in effect until such time as new regulations are promulgated and become effective. It is anticipated that the tentative classification recommendations will be referred back to the panels for ratification or amendment once proposed legislation is enacted. However, the Commissioner believes that these interim procedures established in this notice reflect the intent of proposed legislation and the bulk of the classification work will not have to be duplicated. This will enable the Commissioner to proceed with the final classification process with a minimum of delay once the legislation is enacted.

The Commissioner will issue, in the near future, comprehensive new procedural regulations in 21 CFR Part 2 that will include provisions governing all aspects of the activities of advisory committees, including the device classification panels, such as the preparation of panel records and the release of information coming before the panel.

This notice is published pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040 et seq. as amended (21 U.S.C. 321 et seq.)) and the Public Health Service Act (sec. 1 et seq., 58 Stat. 682 et seq., as amended (42 U.S.C. 201 et seq.)) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: May 12, 1975.

SHERWIN GARDNER,
Deputy Commissioner of Food and Drugs.

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